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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,931	02/15/2001	David Ish-Horowicz	7326-122	8177
20583	7590	07/25/2005	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			KAUFMAN, CLAIRE M	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 07/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/783,931

Applicant(s)

ISH-HOROWICZ ET AL.

Examiner

Claire M. Kaufman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-32, 60, 61, 99-136, 138-146 and 152-166 is/are pending in the application.
- 4a) Of the above claim(s) 114-120, 129, 156 and 157 in part is/are withdrawn from consideration.
- 5) ☒ Claim(s) 152-163 is/are allowed.
- 6) ☒ Claim(s) 29-32, 60, 61, 99-136, 138-146 and 152-166 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 29-32, 60, 61, 99-136, 138-146 and 152-166 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Arguments

The rejection of claims under 35 USC 112, first paragraph, is withdrawn in view of the applicant's arguments and the amendment to the claims.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Claims 114-120, 129, 156 and 157 are objected to for containing non-elected subject matter, namely a fragment comprising the transmembrane domain and EGF-like repeat domain. Note that even though the intracellular domain falls outside the species elected, the examiner has additionally examined claims as they relate to it since it is comprised almost completely within SEQ ID NO:23 (except for sequencing errors—see Examiner's Comments), which sequence the Examiner has examined despite the added search burden.

Drawings

The Brief Description of Figure 6 refers to color in the figure. Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

When a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and a sequence identifier ("SEQ ID NO:X") must be used either in the drawing or in the

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Brief Description of the Drawings. See MPEP § 2422.02. In the instant application, a sequence identifier must be used for the chicken sequences appearing in Figure 11.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29, 30, 60, 61, 107, 108, 109, 113, 114, 129, 131-136, 138 166 and dependent claims 31, 32, 99-106, 110-112, 115-128, 130, 139-146 and 164-165 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29, 30, 60, 61, 107, 108, 109, 113, 114, 129, 131-136, 138 are indefinite as amended because they recite “a second nucleic acid, or its complement,”... “selected from the group consisting of SEQ ID NO:1, the antisense sequence to SEQ ID NO:1,...”, or similar language. The claims are confusing because they recite a nucleic acid or its complement selected from a nucleic acid sequence or its antisense sequence. It is not clear with the amendment whether the “antisense sequence” is meant to be distinguished from the complement. If it is meant to be the same, then it is redundant. See “***Draft Claim***” for a suggestion of rephrasing the claim to make it clear.

Claim 166 is similarly indefinite because instead of reciting “or its complement”, the claim recites “or the antisense sequence...”

Draft Claim

The following claim 29 drafted by the examiner and considered to distinguish patentably over the art of record in this application, is presented to applicant for consideration:

29 (currently amended). An antibody which binds a vertebrate Delta protein, which vertebrate Delta protein is encoded by a first nucleic acid that hybridizes under high stringency conditions to a second nucleic acid, or its complement, the nucleotide sequence of the second nucleic acid

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being selected from the group consisting of SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:11, SEQ ID NO:14, SEQ ID NO:26, and SEQ ID NO:24, said high stringency conditions comprising pretreatment for 8 hours to overnight in a solution containing 6X SSC, 50 mM Tris-HCl (pH 7.5), 1 mM EDTA, 0.02% PVP, 0.02% Ficoll, 0.02% BSA, and 500 µg/ml denatured salmon sperm DNA; hybridization for 48 hours at 68°C in a solution containing 6X SSC, 50 mM Tris-HCl (pH 7.5), 1 mM EDTA, 0.02% PVP, 0.02% Ficoll, 0.02% BSA, and 100 µg/ml denatured salmon sperm DNA; washing for 1 hour at 37°C in a solution containing 2X SSC, 0.01% PVP, 0.01% Ficoll, and 0.01% BSA; and a second washing for 45 minutes at 50°C in a solution containing 0.1X SSC; and which antibody does not bind a *Drosophila* Delta protein.

Claim 29 is exemplary of all claims reciting “antisense sequence”, and the changes shown above for claim 29 would be appropriate for the other similar claims.

Examiner's Comments

The Examiner contacted Applicant's representative William Thomann on July 12, 2005, to determine if the above issues could be addressed with an Examiner's Amendment putting the claims in condition for allowability. The Examiner was requested to proceed with an Office action.

Note that the specification defines “vertebrate” as occurring in vertebrate species, distinguishing the term “vertebrate” from derivatives and analogs thereof. (See, for example, p. 5, lines 20-25: “The present invention relates to nucleotide sequences of vertebrate *Delta* genes (chick and mouse *Delta*, and related genes of other species), and amino acid sequences of their encoded proteins, as well as derivatives (e.g., fragments) and analogs thereof.” And p. 11, lines 14-19: “The invention provides *Delta* genes and their encoded proteins of many different vertebrate species. The *Delta* genes of the invention include chick, mouse, and human *Delta* and related genes (homologs) in other vertebrate species. In specific embodiments, the *Delta* genes and proteins are from vertebrates, or more particularly, mammals.”) Should Applicant disagree with this meaning of “vertebrate”, the claims would be subject to a rejection under 35 USC 112,

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first paragraph, which would not preclude the next Office action from being made final since the issue has been raised here.

Also, as a result of the meaning of “vertebrate” as discussed above and as supported by the prior art, it is noted that claims such as 106 appear to represent inoperative embodiments since SEQ ID NO:23 appears to possess sequencing errors and is not part of any known vertebrate Delta protein. This is the situation with any claim reciting a vertebrate Delta protein which comprises a sequence that does not occur in nature.

Conclusion

Claims 29, 30, 60, 61, 107, 108, 109, 113, 114, 129, 131-136, 138 and 166, as they relate to the species examined, would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Claims 31, 32, 99-106, 110-112, 115-128, 130, 139-146 and 164-165, as they relate to the species examined, would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 152-163 are allowed as they relate to the species examined (however, see claims 156 and 157 which comprise non-elected and non-examined species).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (571) 272-0873. Dr. Kaufman can generally be reached Monday, Tuesday and Thursday from 9:00AM to 3:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (571) 272-0829.

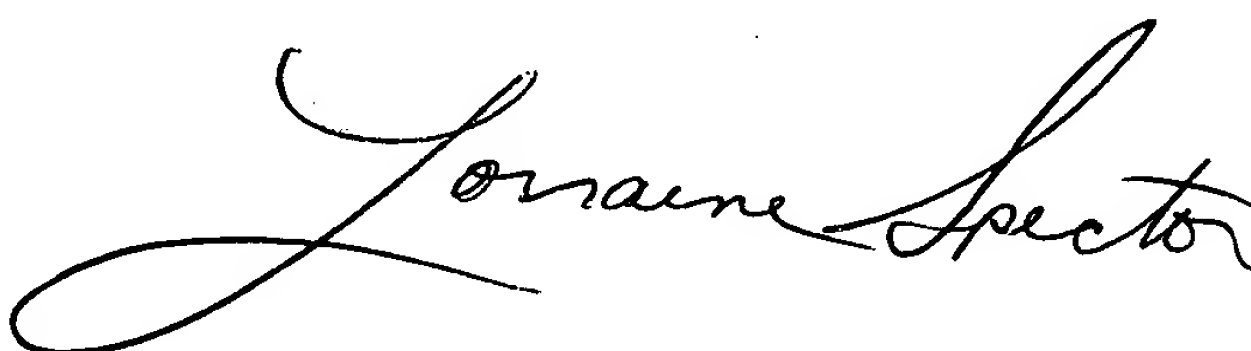
Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Official papers filed by fax should be directed to (571) 273-8300. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

Claire M. Kaufman, Ph.D.


Patent Examiner, Art Unit 1646

July 19, 2005



**LORRAINE SPECTOR
PRIMARY EXAMINER**